K063293

MAR 23 2007

Owner's Name:

Edwards Lifesciences Services GmbH

Address:

Edisonstrasse 6
Unterschleissheim
85716
Germany

Telephone Number: +49 89 95475 203
Fax Number: +49 89 95475 301
Contact Person: Director RA/QA Robert Madjno
Summary Prepared: March 23, 2007

Classification Name:

Regulatory Name: High Permeability Hemodialysis System
Regulation Number: 21 CFR 876.5860
Panel number: 78
Product Code: KDI

Common/Usual Name:

Hemofiltration Line.

Proprietary Name:

Edwards Aqualine Sterile Tubing Set,
Edwards AqualineS Sterile Tubing Set,
and accessories:
Edwards Aquaspike, and
Edwards Aquasafe

Establishment Registration Number:

The device will be manufactured and packed for:
Edwards Lifesciences Services GmbH
Edisonstrasse 6
Unterschleissheim 85716
Germany
by
Haemotronic S.p.A.
16, Via Carreri
Mirandola
Modena 41037
Italy
Establishment Registration Number 9611157

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and

Haemotronic, S.P.A. Advanced Medical Technologies
Via Ugo Roncada 83/e
Carbonara Di Po
Mantova 46020
Italy
Establishment Registration Number 9614854

and sterilized by:

BioSter S.p.A.
9, Via Einaudi
Calcinate
Bergamo 24050
Italy
Establishment Registration Number 3002806603

Substantial Equivalence:

The Edwards Lifesciences Services GmbH Edwards Aqualine Tubing Sets are substantially equivalent in design, use and materials to the:

Baxter Helathcare Corp. - K021615	Baxter Accura Disposable Tubing Set
Baxter Helathcare Corp. - K911315/A	Baxter BM 11 Disposable Tubing Set
Gambro Inc. - K032431	Prisma M100 and M60 Tubing Sets

The Edwards Aqualine Tubing Sets are made of the same materials, by the same processes and contains many of the same components as the Baxter Accura Tubing Set (K021615), which is also manufactured by Haemotronic S.p.A. The significant exception is one of the pressure transducer membranes: this is made of EPDM rubber instead of the butyl rubber used in the Baxter Accura Tubing Set (K021615). The Edwards Aqualine Tubing Sets uses only EPDM rubber for the pressure transducer membranes, whereas the Baxter Accura Tubing Set (K021615) uses both EPDM and butyl rubber for the pressure tranducer membranes.

The Edwards Aqualine Tubing Sets, the Baxter Accura Tubing Set (K021615), the Baxter BM11 Tubing Set (K911315/A) and the Gambro Prisma M100 and M60 Tubing Sets (K032431) are all single use and intended for disposal after each session.

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The Edwards AqualineS Tubing Set is indicated for use where a lower flow rate and lower priming volume are desired than with the Edwards Aqualine Tubing Set. Other manufacturers offer a tubing set with a lower volume as an alternative, for example: Gambro Prisma M100 and M60 Tubing Sets (K032431).

The Edwards Aqualine Tubing Sets are sterilized under the same conditions as the Baxter Accura Tubing Set (K021615).

Description of Product:
The Edwards Aqualine Tubing Sets are designed for use with the Baxter Accura System (K021615).

The Edwards Aqualine Tubing Sets are indicated for use with the Baxter Accura System (K021615) for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. The Edwards Aqualine Tubing Sets may also be used in Therapeutic Plasma Exchange (TPE) therapies.

The Edwards Aqualine Tubing Sets and the Baxter Accura System (K021615) are indicated for use in a clinical setting and not for home use.

The Edwards AqualineS Tubing Set is indicated for use where a lower flow rate and lower priming volume are desired than with the Edwards Aqualine Tubing Set. The Edwards AqualineS Tubing Set is particularly suitable for therapies in which a low blood flow or a low priming blood volume is desired, such as SCUF or low volume for congestive heart failure therapy. The selection of the Edwards Aqualine Tubing Set or the Edwards AqualineS Tubing Set is to be determined by clinical preference.

The Edwards AqualineS Tubing Set is different from the Edwards Aqualine Tubing Set in total volume, length, and inner and outer diameters.

The differences between the Edwards Aqualine Tubing Sets and the Baxter Accura Tubing Set (K021615) are not significant for their intended use, and do not involve any potential risk related to the use of the Edwards Aqualine Tubing Sets with the Baxter Accura System (K021615).

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The tubing pathway can be split up in to five separate sections:

- Access Blood path (Red)
- Return Blood path (Dark Blue)
- Filtrate (Effluent) path (Yellow)
- Dialysate Solution path (Green)
- Replacement (Substitution) path (Light Blue)

The Edwards Lifesciences Services GmbH Edwards Aqualine Sterile Tubing Set is used with the Baxter Accura System for the following therapies:
SCUF (Slow continuous ultrafiltration)
CVVH (Continuous veno-venous hemofiltration)
CVVHD (Continuous veno-venous hemodialysis)
CVVHDF (Continuous veno-venous hemodiafiltration)
TPE (Therapeutic plasma-exchange)

The Edwards Lifesciences Services GmbH Edwards Aqualine Sterile Tubing Set will be packaged in a sterile pack. An expiration date has been determined based on real time tests.

Intended Use:

The Edwards Aqualine Tubing Set is indicated for use with the Baxter Accura System for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. The Edwards Aqualine Tubing Set may also be used in Therapeutic Plasma Exchange (TPE) therapies. The Edwards Aqualine Tubing Set and the Baxter Accura System are indicated for use in a clinical setting and not for home use. The Edwards AqualineS Tubing Set is indicated for use where a lower flow rate and lower priming volume are desired.

The Edwards Aquaspike tubing set is indicated for use with the Edwards Aqualine Tubing Set and the infusion bags used for continuous solute and /or fluid removal in patients with acute failure or fluid overload. Aquaspike is used to connect up to four infusion bags with the Aqualine Tubing

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The Edwards Aquasafe is an Aqualine accessory (a three 25ml-empty-sterile bags disposable device) and it is used when it is necessary to decrease the pressure level inside Aqualine, prior its removal from the machine.

Bench Testing:

Functional testing has been conducted with the Edwards Aqualine Tubing Sets on the Baxter Accura System (K021615).

Rolling tests (mechanical resistance during the rolling pump action) have been conducted with the Edwards Aqualine, Edwards AqualineS and Baxter Accura (K021615) Tubing Sets.

The expiration date has been established by a series of real-time tests conducted over a 5 year period.

Tensile Strength Testing was conducted as part of the expiration date tests.

Conclusions:

Based on the numerous common features and comparative testing, Edwards Lifesciences Services GmbH believes the Edwards Aqualine Tubing Sets are substantially equivalent to the predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Edwards Lifesciences Services GmbH
c/o Mr. Neil R. Armstrong
Regulatory Affairs Advisor
Meddiquest Limited
Business & Technology Center
Bessemer Drive
Stevenage, Hertsfordshire
UNITED KINGDOM SG1 2DX

MAR 23 2007

Re: K063293
Trade/Device Name: Edwards Aqualine Sterile Tubing Set; Edwards AqualineS Sterile Tubing Set; Edwards Aquaspike; and, Edwards Aquasafe
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FJK
Dated: February 28, 2007
Received: March 7, 2007

Dear Mr. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): **K063293**

Device Name: **Edwards Aqualine Sterile Tubing Set, Edwards AqualineS Sterile Tubing Set, Edwards Aquaspike and Edwards Aquasafe**

Indications for Use:

The Edwards Aqualine Tubing Set is indicated for use with the Baxter Accura System for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. The Edwards Aqualine Tubing Set may also be used in Therapeutic Plasma Exchange (TPE) therapies. The Edwards Aqualine Tubing Sets are indicated for use in a clinical setting and not for home use. The Edwards Aqualine S Tubing Set is indicated for use where a lower flow rate and lower priming volume are desired.

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The Edwards Aquasafe is an Aqualine accessory (a three 25ml-empty-sterile bags disposable device) and it is used when it is necessary to decrease the pressure level inside Aqualine, prior its removal from the machine.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063293